

REMARKS

In the Office action dated November 19, 2002, claims 25-54 were rejected. Claims 25-26, 28-35, and 37-39 are pending herein as claims 27, 36, and 40-54 are cancelled. Claims 25-26, 28-30, 33, and 38-39 are amended. Support for the amendments are found throughout the specification and in the claims as filed and therefore no new matter has been added by way of amendment. The amendments are introduced in response to rejections under 35 U.S.C. § 112, second paragraph, and it is respectfully submitted that these amendments are non-narrowing. Comments, objections, and rejections set forth in the Office action are addressed in the following remarks.

Election and Claims Under Examination

The applicants appreciate that the Office examined all of claims 25-54 in view of the election of Group III with traverse. The cancellation of claims 1-24 is noted and the applicants appreciate reconsideration of claims 25-26, 28-35, and 37-39 in view of the remarks set forth herein.

Matters of Form

The Office noted in the Office action that the title of the invention is not clearly directed to the subject matter claimed. The title of the application is amended herein such that it is clearly directed to the claimed subject matter. The applicants appreciate the Office's recognition of the claim to priority under 35 U.S.C. § 119 to British patent application no. 9904585.8.

Rejection under 35 U.S.C. § 101

The Office rejected claims 40-50 under 35 U.S.C. § 101. It is respectfully submitted that this rejection is moot in view of the cancellation of claims 40-54 herein. Accordingly, it is respectfully requested that the Office withdraw the rejection under 35 U.S.C. § 101.

Rejections under 35 U.S.C. § 112, Second Paragraph

The Office rejected claims 25-54 under 35 U.S.C. § 112, second paragraph. It is respectfully submitted that the rejection is moot in view of the claim amendments and cancellations, and in some instances, the rejection is respectfully traversed.

With regard to missing essential steps, claims 27 and 40-54 are canceled herein, and therefore the rejection is moot. With regards to the alleged indefiniteness of claim 25, the clause “whereby the correlation between a phenotype and a genotype is identified” has been added to relate the body of the claim to the preamble. Also, claim 25 has been amended to specify that “the phenotype characteristic is associated with a genotype characteristic,” which as described hereafter with regard to the rejection under 35 U.S.C. § 112, first paragraph, is fully enabled and understood by the person of ordinary skill in the art given the teachings in the specification and in the art. Thus, determining the association between a phenotype and a genotype is affirmatively claimed and well-understood by the person of ordinary skill in the art.

The terms “comply,” “such as,” “(asthma),” “location,” and “enabling” are no longer present in claims 25, 28, 29, 37, and 39 and are removed by cancellation of claims 36 and 40-54. Therefore, the rejection of these claims under 35 U.S.C. § 112, second paragraph, is moot. The alleged lack of antecedent basis in claims 27 and 28 is remedied by the cancellation of claim 27 and the amendment of claim 28. Thus, the amendments and cancellation of certain claims render moot the rejections under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. § 112, First Paragraph

The Office rejected claims 25-54 under 35 U.S.C. § 112, first paragraph, as it was alleged that the claimed subject matter was not enabled by the specification. The Office specifically alleged that certain steps set forth in claims 25, 33, and 39 are not disclosed in the specification. The rejection is traversed with regard to pending claims 25-26, 28-35 and 37-39. The particular steps in these claims identified by the Office are discussed hereafter.

The Office noted that in claim 25 the step of “identifying records from a database for individuals that comply with the selected phenotype characteristic,” was not provided for in the specification. This step no longer is present in claim 25 due to the amendment in response to the rejection of this term under 35 U.S.C. § 112, second paragraph, as noted above. Instead, the claim now reads “identifying records from the database for individuals having the selected phenotype characteristic,” which is a step routinely carried out by any database user as the user simply selects the phenotype characteristic and searches the database for individuals that have the characteristic. Thus, this step in claim 25 does not require any experimentation, any database structure allows for the ready selection of individuals based on a phenotype, and there is no unpredictability for practicing this step. Accordingly, this step in claim 25 is fully enabled.

The Office also drew attention to the step in claim 25 of “taking account of confounding information.” The specification clearly describes confounding information on page 3, line 14 to page 4, line 9 and clarifies in one embodiment on page 12, lines 14-15 that confounding environmental and age related data can be utilized to eliminate the effects of age and environment on variations and phenotype. The specification also clearly describes on page 13, line 19 to page 14, line 13 that information pertaining to twins can be utilized to remove the effects of age and environment on variations and phenotype. Thus, the specification clearly teaches a wide array of confounding factors and manners in which those factors can be factored into a genetic association analysis. This clear teaching is supplemented by the high level of skill of the person typically practicing the claimed methods (*e.g.*, often a Ph.D. level scientists or statistician) and the extensive teachings in the prior art (*e.g.*, page 49, line 28 to page 53, line 17 of WO 95/212619 cited by the Office in the 35 U.S.C. § 102 rejection discussed hereafter) demonstrates that “taking account of the confounding information in the database” does not require undue experimentation and is enabled by specification.

It is noted that when the person of ordinary skill in the art is provided with a database comprising a plurality of records containing phenotype information, genotype information, and confounding information, that person is prepared to run several genetic association analyses to

determine whether the confounding information bears on the outcome of the association between the genotype and the phenotype. This preparedness to screen several data sets was not considered undue experimentation by the Court of Appeals for the Federal Circuit in *In re Wands*, which is cited by the Office to highlight the *Foreman* factors addressed herein. As the *Wands* court found that the skilled artisan similarly was prepared to screen several hybridomas to identify the small fraction of those that generated an antibody of interest, the Office should find here that the specification fully enables the claimed methods without requiring undue experimentation.

With regard to the term “genotype information is selected from . . . inferred nucleotide sequences” in claim 33, the claim now is directed to “nucleotide sequences” in view of the rejection under 35 U.S.C. § 112, second paragraph. Thus, the rejection under 35 U.S.C. § 112, first paragraph, is moot with respect to this term. The Office also stated that the terms “record of variation” and “reference sequence” were not enabled in claim 33. These terms also are not present in claim 33 as a result of amendments in response to the rejection under 35 U.S.C. § 112, second paragraph. Therefore, the rejection under 35 U.S.C. § 112, first paragraph, also is moot.

In claim 39, the Office objected to the term “contact information would enable the individual to be contacted and retested in person.” This term has been removed from claim 39, and instead, claim 39 specifies that the database includes personal contact information of individuals. Accordingly, claim 39 is fully enabled by the specification because contact information for the individual can be readily obtained from an individual and requires no further steps or experimentation.

With regard to claims 28, 29, 40, 43, 44 and 53 (*see* Office action page 5 last paragraph), the pending claims have been amended in a response to the rejections under 35 U.S.C. § 112, second paragraph to specify that the “selected anti-characteristic is associated with a genotype characteristic” in a database. Once the person of ordinary skill in the art is provided with a database having a plurality of records containing phenotype information, genotype information, and confounding information, methods for associating phenotype characteristics with genotype

characteristics are well-known in the art (*i.e.*, see page 49, line 28 to page 53, line 17 of WO 95/21269 in view of the high level of skill for the ordinary artisan). The present specification provides guidance for generating associations on page 28, lines 22-23 by describing an embodiment of the claimed methods in which the person of ordinary skill in the art uses “a mean effect model,” which is a standard statistical analysis readily practiced by the skilled artisan. Thus, association methodology was well-known in the art at the time the patent application was filed and this specification provides guidance as to how the skilled artisan generates such an association. Therefore, this specification fully enables the pending claims.

Rejection Under 35 U.S.C. § 102

Claims 25-31, 33, 36, 37, 40-46, 48, and 51-53 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Perlin *et al.* (WO 95/21269). The rejection is respectfully traversed. Perlin discusses genetic procedures for developing dense genotype maps. While Perlin discusses methods of correlating phenotypes with certain genotype information from these dense genotype maps, there is no mention in Perlin that the genotype data can be combined with phenotype information and confounding information in a single database to generate associations between a phenotype and a genotype.

Claim 25 specifies that the database comprises a plurality of records containing phenotype information, genotype information, and confounding information, and that a phenotype characteristic is associated with a genotype characteristic taking account of confounding information in the database. This specification notes several advantages to this approach. On page 3, lines 24-26, the specification states that one advantage is that account of the confounding factors leads to more reliable correlations. Also on page 10, lines 16-23, the specification states that the claimed method overcomes a disadvantage of prior art database by allowing the database to be used for multiple future association studies without requiring further data gathering because comprehensive phenotype, genotype information, and confounding information already has been entered into one database. Because Perlin does not disclose a

single database having a plurality of records containing phenotype information, genotype information, and confounding information, the database disclosed in Perlin cannot be used to practice the claimed methods. As a result, the database described in Perlin cannot realize the advantages of using the database described in the present application. Thus, Perlin does not disclose the claimed methods, and therefore, it is respectfully requested that the rejection under 35 U.S.C. § 102(b) be withdrawn.

CONCLUSIONS

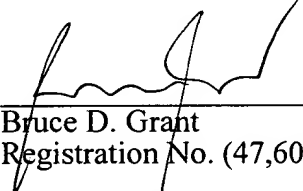
Claims 25-26, 28-35, and 37-39 are pending, and claims 25-26, 28-30, 33, and 38-39 are amended. It is respectfully submitted that the non-narrowing amendments to the claims overcome the rejections under 35 U.S.C. § 112, second paragraph, and that the pending claims are fully enabled in accordance with 35 U.S.C. § 112, first paragraph. It is also respectfully submitted that the pending claims are novel and not anticipated by Perlin. Accordingly, it is respectfully submitted that the pending claims are allowable and a notice to that effect is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 532592001200.

Respectfully submitted,

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